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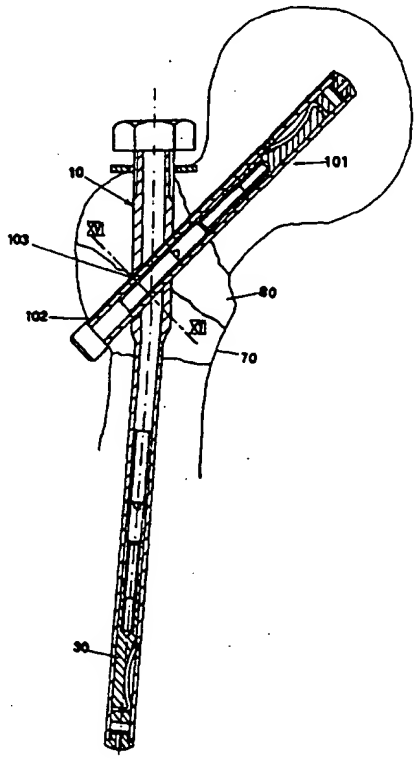
(54) Title: INTRAMEDULLARY NAIL FOR THE OSTEOSYNTHESIS OF BONE FRACTURES

(57) Abstract

Intramedullary nail to be used in orthopedics comprising: a substantially cylindrical tubular body (1); at least one anchoring device (3) placed into said cylindrical body (1) provided with two or more longitudinal cavities (32), each of said cavities being shaped in such a way as to be suitable for housing a hook (33) with arched tip (34) pointed towards the outer side of the tube and facing a slot (6) positioned on the cylindrical surface of said tubular body, said hook (33) being movable with respect to the housing cavity (32) during the sliding of the anchoring device with respect to the tube; a manoeuvring element (4) for said anchoring device suitable to ensure the longitudinal sliding, in the two directions, of said at least one anchoring device (3), causing the coming out of the hooks (33) or their introduction into the openings provided on the tubular body, respectively; a drilled bushing (9) sliding on the non-cylindrical end of said tubular body and having at least one arched lip (91) for the contact with the bone in which said nail is inserted, said bushing cooperating with a screw (2), the head of which rests on said bushing and screws onto the thread (12) provided inside the tubular body in correspondence with the non-cylindrical length.



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INTRAMEDULLARY NAIL FOR THE OSTEOSYNTHESIS OF BONE FRACTURES

The invention concerns a tubular intramedullary nail to be used in orthopedics for the reduction of bone fractures.

It is well known that in orthopedic surgery tubular metal rods called"nails" to be inserted in the fractured bone after drilling the medullary canal of the bone itself are used in most cases for the treatment of fractures, especially fractures of the long bones. In order to avoid the rotation of the fragments and their shortening in multifragmented fractures. The known technique requires the intersection of said nail by means of anchoring screws that pass through apposite holes. The insertion of the nail and, above all, the distal locking of the nail itself on the fragments of the fractured bone are rather complex operations, due also to the fact that it is often difficult to center the screws to be inserted on the nail holes.

Another drawback connected with the known technique is represented by the fact that during the fracture consolidation time the nail, locked as it is through transverse screws, actually prevents any relative movement of the fractured bone fragments in the longitudinal direction. This is obviously a limitation of the known technique, in fact, since a moderate physiological absorption of the fractured parts takes usually place, a dynamic compaction is practically impossible. Therefore, the impossibility to bring the two bone fragments under dynamic load near each other prolongates the fracture consolidation time.

The invention aims at eliminating the above mentioned drawbacks. One of the aims of the invention is the implementation of a new nail that should prevent the bone fragments from rotating, with no need to lock the nail itself by means of a series of transverse screws.

A further aim is the implementation of a nail provided with all the devices necessary to anchor the fragments. Though fixed to the fractured bone, said nail should not prevent the dynamic compaction of the fragments themselves when the limb is subjected to axial dynamic load, for example when the body weight rests on the limb itself.

Another goal of the invention is the implementation of a nail that can be easily removed from the bone inner cavity when this is necessary for any reason whatsoever.

The aims described above and others that will be better described here below are achieved through the implementation of an intramedullary nail to be used in

orthopedics that, according to the main claim, is characterized in that it comprises:

- a substantially cylindrical tubular body, having end the outer shape of which is not cylindrical for a length;
- at least one substantially cylindrical anchoring device, free to slide inside said tubular body provided with two or more longitudinal cavities, each of said cavities being shaped in such a way as to be suitable for housing a hook with arched tip pointed towards the outer side of the tube and facing a slot positioned on the cylindrical surface of said tubular body, said hook being movable with respect to the housing cavity during the sliding of the anchoring device with respect to the tube;
- a manoeuvring element for said at least one anchoring device, to be operated by means of a manual tool, housed inside said tubular body and suitable to ensure the longitudinal sliding, in the two directions, of said at least one anchoring device, which cause the coming out of the hooks or their introduction into the openings provided on the tubular body, respectively;
- a drilled bushing, shaped so that it can slidingly couple with the non-cylindrical end of said tubular body and having at least one arched lip for the contact with the bone in which said nail is inserted, said bushing cooperating with a screw, the head of which rests on said bushing and screws onto the thread provided inside the tubular body in correspondence with the non-cylindrical length.

To advantage, according to the invention the anchoring device positioned inside the intramedullary nail locks the distal fragment part by means of two or more hooks that come out of the intramedullary nail during the operation of the manoeuvring device. The intramedullary nail can be provided with one or more anchoring devices, for example two, depending on the type of fracture that must be treated.

As far as simple fractures (transverse, oblique, etc.) are concerned, only one anchoring device can be used inside the intramedullary nail and its action will involve the lower part of the fragment. The compaction of the two fragments is achieved through the action of the screw that rests against the bushing on the proximal end of the intramedullary nail. Said bushing, the body of which is coupled with the non-cylindrical part of the nail positioned inside the bone, rests on the outer surface of the bone by means of one or more lips, thus preventing the rotation of the two fragments and at the same time bringing the lower part of

the fragment near the upper part, until obtaining their compaction.

As will be better illustrated below, the fact that the bushing can slide with respect to the end of the intramedullary nail makes it possible to obtain the compaction of the fragment even during the fracture consolidation period, since the axial dynamic load of the limb pushes the lower fragment againt the upper fragment, this being possible thanks to the relative movement between the bushing and the upper end of the intramedullary nail.

Further characteristics and details of the invention will be better highlighted in the following description of the invention in question, illustrated in the attached drawings, wherein:

- Figure 1 shows the application of the nail object of the invention to a thighbone with simple fracture;
- Figure 2 shows the thighbone of Fig. 1 after compaction;
- Figure 3 shows the nail object of the invention provided with two anchoring devices in a thighbone with a multifragmented fracture before compaction;
- Figure 4 shows the thighbone of Fig. 3 after compaction;
- Figure 4a shows the thighbone of Fig. 3 and 4 compacted with the nail of Fig. 2 and stabilized by means of a transverse screw;
- Figure 5 is an exploded view of the anchoring device and of the manoeuvring device with which the intramedullary nail object of the invention is provided;
- Figure 6 shows a section of the nail object of the invention comprising one anchoring device only;
- Figure 7 is a variant of Figure 6, in which the anchoring device is positioned so that the coming out of the hook tips is reversed with respect to that shown in Fig. 6;
- Figure 8 shows a section of the nail object of the invention associated with a transverse screw to be used for multifragmented diaphyseal fractures, as shown in Fig. 4a;
- Figure 9 is a top view of the detail of the lip with which the nail bushing is provided;
- Figures 10 and 11 show the sections of two nails according to the invention, each one being provided with two anchoring devices directed convergently and divergently, respectively;
- Figure 12 shows a particular execution of the nail object of the invention used for per-subtrochanteric fractures of the thighbone;

- Figure 12a shows a particular execution of the nail used for the same fractures illustrated in Fig. 12;
- Figure 13 shows the nail object of the invention used for basal neck fractures;
- Figures 14 and 15 show an exploded view and a section, respectively, of an application of the bushing and screw associated to the nail object of the invention;
- Figure 16 shows a section of the transverse nail of Fig. 12 according to the line XVI-XVI.

With reference to the above mentioned figures, particularly to Figures 5 and 6, it can be observed that the nail object of the invention, a section of which is shown in Figure 6, comprises a tubular body, indicated as a whole by 1, the end 11 of which has external octagonal shape obtained from the outer diameter of the tubular body 1 through machining. The inside of said tube 1 is provided with two threads, one in correspondence with the external octagonal area 11, said thread being indicated by 12 and used, as will be explained below, for screwing the screw 2. The other thread is situated in the inner body of the tube 1 and is indicated by 13. This thread occupies only one part of the tubular body, and precisely the area included between the references from 131 to 132, on which the anchoring device 3 will be screwed.

Said anchoring device, indicated as a whole by 3 and visible in detail in Figure 5, comprises a cylinder 31 provided with four longitudinal cavities 32, only two of which can be seen in the exploded view of Figure 5, each of said four longitudinal cavities being suitable for receiving a hook indicated by 33, said hook having arched shaped and being provided with a tip 34 and an opposite end with substantially round section 35 that fits into a hole 36 made on the bottom of the longitudinal cavity 32. The cylindrical body 31 comprises also a threaded housing 37 suitable for receiving the manoeuvring element 4 that will ensure the longitudinal movement of the anchoring device in both directions. On its opposite end the cylindrical body 31 is provided with a slot for a screwdriver indicated by 38. The anchoring device cooperates with a manoeuvring device, indicated as a whole by 4, which, as can be seen in Figure 5, comprises a threaded rod with double diameter 41 and 42, respectively, where, in the example, the thread 41 of the longer diameter is a right thread and the thread 42 of the shorter diameter is a left thread. The thread 41 screws on the inner thread 13 belonging to the tubular body 1, while the thread 42 screws on the threaded

hole 37 belonging to the anchoring device 3.

The manoeuvring element 4 is directly coupled with the anchoring device 3 complete with the hooks 33 and inserted into the tube 1. As shown in Figures 6 and 7, the end opposite the non-cylindrical length of the tube 1 is closed with a threaded plug 5. This plug also serves to stop the sliding of the anchoring device during its manoeuvre, in fact it acts as end of stroke.

With reference to either Figure 6 and Figure 7, when the tips 34 of the hooks 33 are near the slots 6 provided on the surface of the tubular body 1, the rotation of the anchoring device 3, obtained for example through the insertion of the tip of a screwdriver into the slot 38 of the tubular body 31, will make it possible to direct the anchoring device correctly, making the tips 34 of each hook come out through the slots 6.

It is clear that a successive operation with a manual tool not represented in the drawings, for example with an hexagon spanner, on the hexagon 43 of the manoeuvring element 4, will ensure the rotation of said manoeuvring element and therefore the travel in either directions, according to the rotation direction of said manoeuvring element, of the anchoring device 3.

With reference to Figure 6, when the manoeuvring element 4 moves in the direction of the arrow, the anchoring device is pulled upwards and consequently the hooks 33 come out of the slots 6 as illustrated in Figure 2, which shows the application of the nail object of the invention to a thighbone with simple fracture. In this case the hooks 33 of the nail extend from the slots 6 upwards, the type of nail being that shown in section in Figure 6. In the case of a simple fracture, the extension of the hooks 33 towards the outside of the nail and therefore in anchoring position with respect to the bone takes place in the distal part of the bone and before the compaction of the two fragments. In fact, the sequence of the operations to be performed with the nail object of the invention basically consists in the introduction of the nail in the medullary canal of the bone prepared in advance. Successively the manoeuvring element is operated, so that the anchoring device locks the distal fragment. The two fragments indicated by 7 and 8 in Figure 1 are then brought near each other through the pressure exerted by the head of the screw 2 onto the bushing 9, which is provided with a hole having the same shape as the end 11 of the tubular body 1, in this case octogonal, and the body of which is housed inside the bone. As a consequence of this, the bushing 9 can only slide longitudinally downwards, but cannot rotate. If

the bushing slides downwards, the lip 91 integral with the upper part of the bushing 9 comes to rest on the outer part of the bone 8. In this way, any screwing of the screw 2 can only move the whole tubular body 1 of the nail upwards and therefore compact the two fragments 7 and 8, as shown in Figure 2. Therefore, in the case of a simple fracture, as shown in Figures 1 and 2, it is sufficient to use a single anchoring device 3 inserted in the nail object of the invention, since said device ensures the locking of the fragment 7, while the locking of the fragment 8 in rotation is due to the external action of the lip 91 belonging to the bushing 9.

During the patient's convalescence, the axial dynamic load to which the two fragments are subjected improves their compaction, said compaction being facilitated by the presence of the nail object of the invention, in fact the whole nail can lift, since it can slide on the groove of the bushing 9.

In the case of multifragmented fractures, as shown in Figures 3 and 4, the nail must be provided with at least two anchoring devices 3. More specifically, it can be observed that the nail object of the invention used for the fracture shown in Figures 3 and 4 is the nail a section of which is shown in Figure 11, where two anchoring devices 30 and 301 opposite to each other and operated by the respective manoeuvring elements 40 and 401 are provided. Figure 10 shows a further variant, in which the nail is also provided with two anchoring devices 30 and 301, which however are directed convergently and not divergently as in Figure 11. The advantage ensured by the double locking that can be obtained for multifragmented fractures, as already said, is evident. Figure 3 shows the multifragmented bone with the nail with double anchoring device. Obviously, the first device 30 must be firstly operated, then the bone fragments are to be compacted and then the second extension or locking of the second anchoring device must be performed. After this, the nail can be definitively fixed with the bushing 9, properly directing the lip 91.

If, for safety reasons, it is necessary to carry out the proximal locking of the nail object of the invention with a transverse screw 20, this can be easily made, since the nail object of the invention is al provided with a transverse hole 21 for the insertion of said screw, as shown in Figure 4a and in section in Figure 8.

In the case of fractures of the thighbone, as those shown in Figure 12, where a per-subtrochanteric fracture is shown, two nails according to the invention, indicated by 10 and 101, respectively, can be inserted in the thighbone. In this case the nail 10 is slightly bent to follow the shape of the bone and is provided

with one anchoring device 30 only, for the distal locking. A further nail 101, provided with only one anchoring device 30 as well, is used to replace the traditional cephalic screw, so that the anchorage of the device through the hooks on a bone part that is far from the fracture is ensured. It must be observed that the use of the nail 101 prevents the rotation of the proximal part of the fracture. It must also be observed that the rotation between the nail 101 and the nail 10 is prevented by the presence of a rod 102 housed in a lowered longitudinal impression 104 present on the outer surface of the nail 101, which corresponds to an equal cavity 105 on the hole 103 belonging to the nail 10. This can be seen in Figure 16, which shows the section of the nail 101 according to the line XVI-XVI.

Figure 12a shows the nail object of the invention with an angular plate 71 to replace the bushing. This plate presents a substantially flat longitudinal rod 72 that rests on the thighbone and is connected with a tubular body 73 that couples with the non-cylindrical part of the nail and on which the head of the screw 2 rests to achieve the compaction of the fracture.

Figure 13 shows the introduction of the nail object of the invention in a basal neck fracture. In such a case, it is important that in the part 81 the anchorage with the nail hooks takes place in the thighbone part with longer diameter, therefore it is necessary to use a nail having the hook tips directed towards the terminal part of the nail itself, that is, a nail of the type shown in Figure 7, while in the operation to which Figure 12 refers a nail of the type shown in Figure 6 is used. Figures 14 and 15 show a special bushing shaped like an expansion washer, indicated by 50 and having two symmetrical lips 51 and a non-cylidnrical hole 53, said bushing resting against the surface of the fragment 71 through the pressure of the head 51 of the screw 52 that screws on the tubular element of the nail 100.

CLAIMS

1) Intramedullary nail to be used in orthopedics, **characterized in that** it comprises:

- a substantially cylindrical tubular body (1), having an end the outer shape of which is not cylindrical for a length (11);
- at least one anchoring device (3) having a substantially cylindrical body (31) provided with two or more longitudinal cavities (32), each of said cavities being shaped in such a way as to be suitable for housing a hook (33) with arched tip (34) pointed towards the outer side of the tube and facing a slot (6) positioned on the cylindrical surface of said tubular body, said hook (33) being movable with respect to the housing cavity (32) during the sliding of the anchoring device with respect to the tube;
- a manoeuvring element (4) for said anchoring device, to be operated by means of a manual tool, housed inside said tubular body and suitable to ensure the longitudinal sliding, in the two directions, of said at least one anchoring device (3), causing the coming out of the hooks (33) or their introduction into the openings provided on the tubular body, respectively;
- a drilled bushing (9), shaped so that it can slidingly couple with the non-cylindrical end of said tubular body and having at least one arched lip (91) for the contact with the bone in which said nail is inserted, said bushing cooperating with a screw (2), the head of which rests on said bushing and screws onto the thread (12) provided inside the tubular body in correspondence with the non-cylindrical length.

2) Intramedullary nail according to claim 1), **characterized in that** during the movement through the opening (6) present on the tubular body, each hook (33) belonging to each anchoring device (3) lifts from its cavity (32) keeping its end (35) opposite the tip inserted in a radial hole (36) present on an end of the bottom of said cavity.

3) Nail according to claims 1) or 2), **characterized in that** the manouevring device (4) of said anchoring device is a threaded rod with double diameter (41, 42), the shorter diameter (42) being provided with a first thread suitable for coupling with a threaded hole (37) present at the end of the anchoring device (3), the longer diameter (41) being provided with a second thread, reversed with respect to the first one and suitable for engaging on a corresponding thread (13) present on the inner wall of the tubular body and an

axial housing (43) suitable for receiving the head of a manoeuvring spanner.

4) Nail according to anyone of the previous claims, **characterized in that** it is provided with a transverse hole (21) suitable for receiving a screw (20) that guarantees a further locking.

5) Nail according to anyone of the previous claims, **characterized in that** the outer initial length of said nail has the shape of a parallelepiped.

6) Nail according to anyone of the previous claims, **characterized in that** it is provided with two anchoring devices (30, 301) positioned in opposite directions, so that the respective hooks come out convergently or divergently with respect to one another.

7) Nail according to anyone of the previous claims, **characterized in that** it is provided with a closing plug (5) on its bottom.

8) Nail according to anyone of the previous claims, **characterized in that** the bushing has the shape of a washer (50) with two symmetrical lips (51) suitable for resting on the bone to be compacted.

9) Nail according to anyone of the claims from 1) to 7), **characterized in that** the bushing takes the shape of a plate (71) presenting a substantially flat longitudinal rod (72) that rests on the thighbone and is connected with the tubular body (73) that couples with the non-cylindrical part of the nail and against which the head of the screw (2) interacting with said nail rests.

10) Nail (10) according to claim 1), **characterized in that** it is provided with a transverse hole (103) through which a second nail (101) is inserted, the rotation of said second nail (101) being prevented by a rod (102) housed in longitudinal impressions (104, 105) facing each other and located on the hole (103) of said nail and on the outer surface of said second nail.

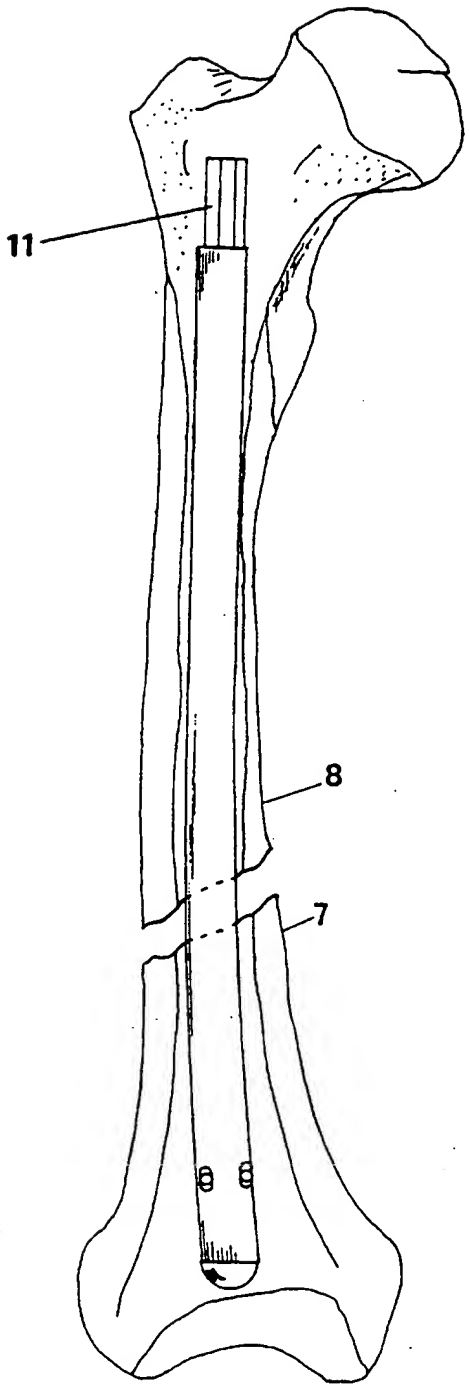

FIG.1

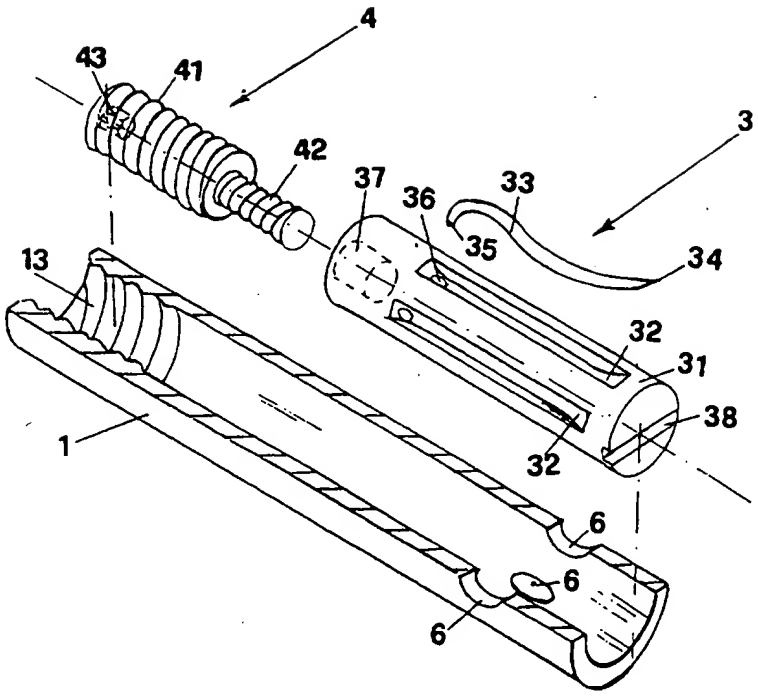

FIG.5

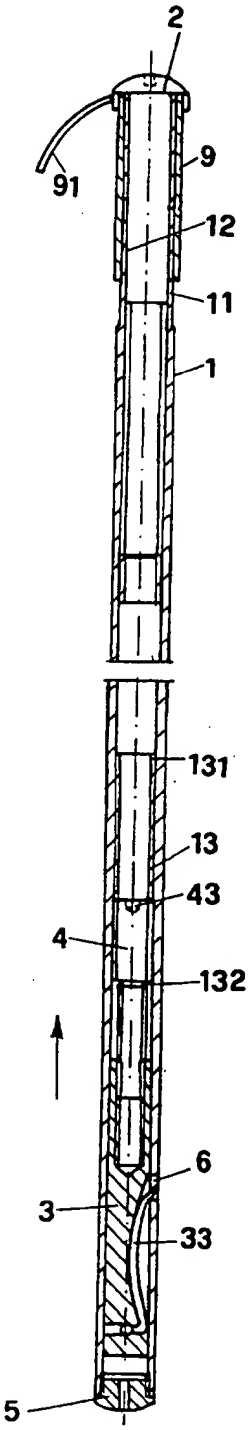

FIG.6

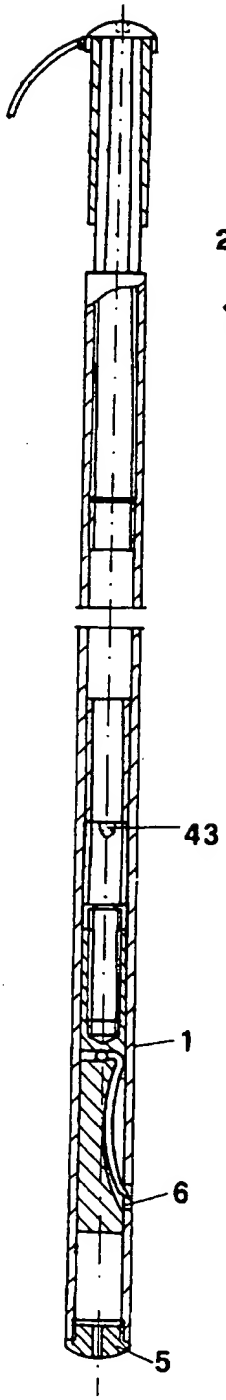

FIG.7

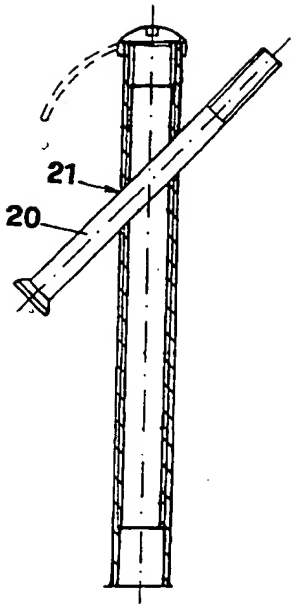

FIG.8

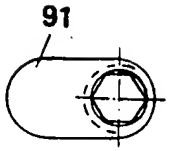

FIG.9

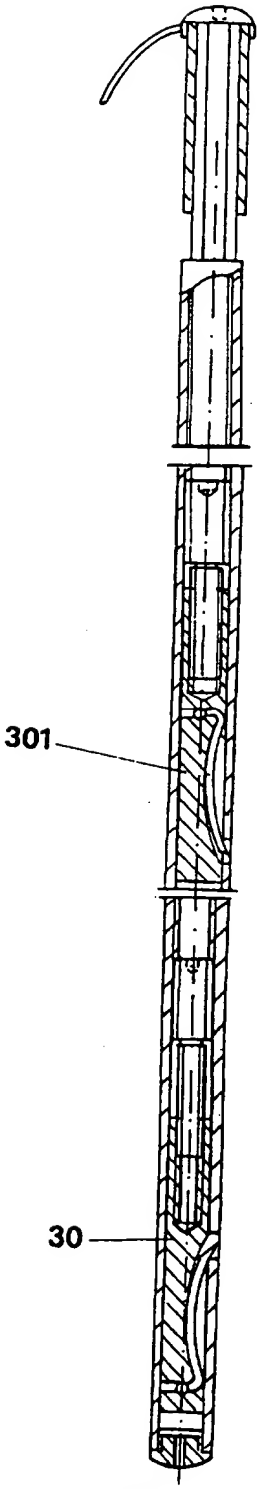

FIG.10

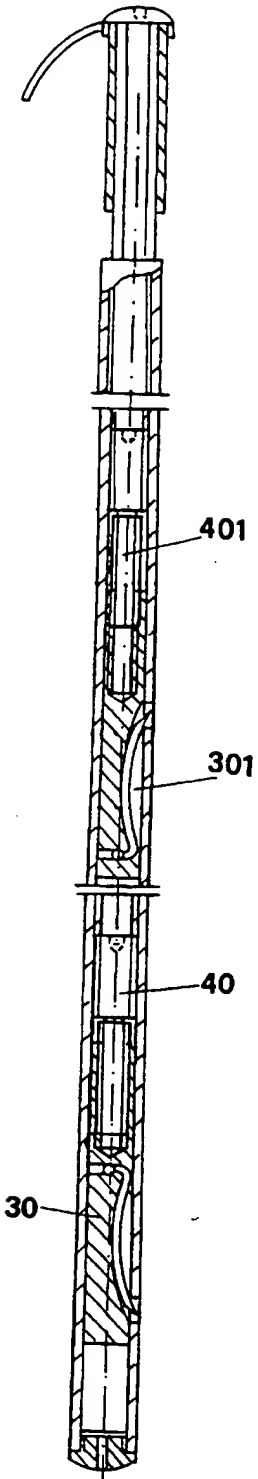

FIG.11

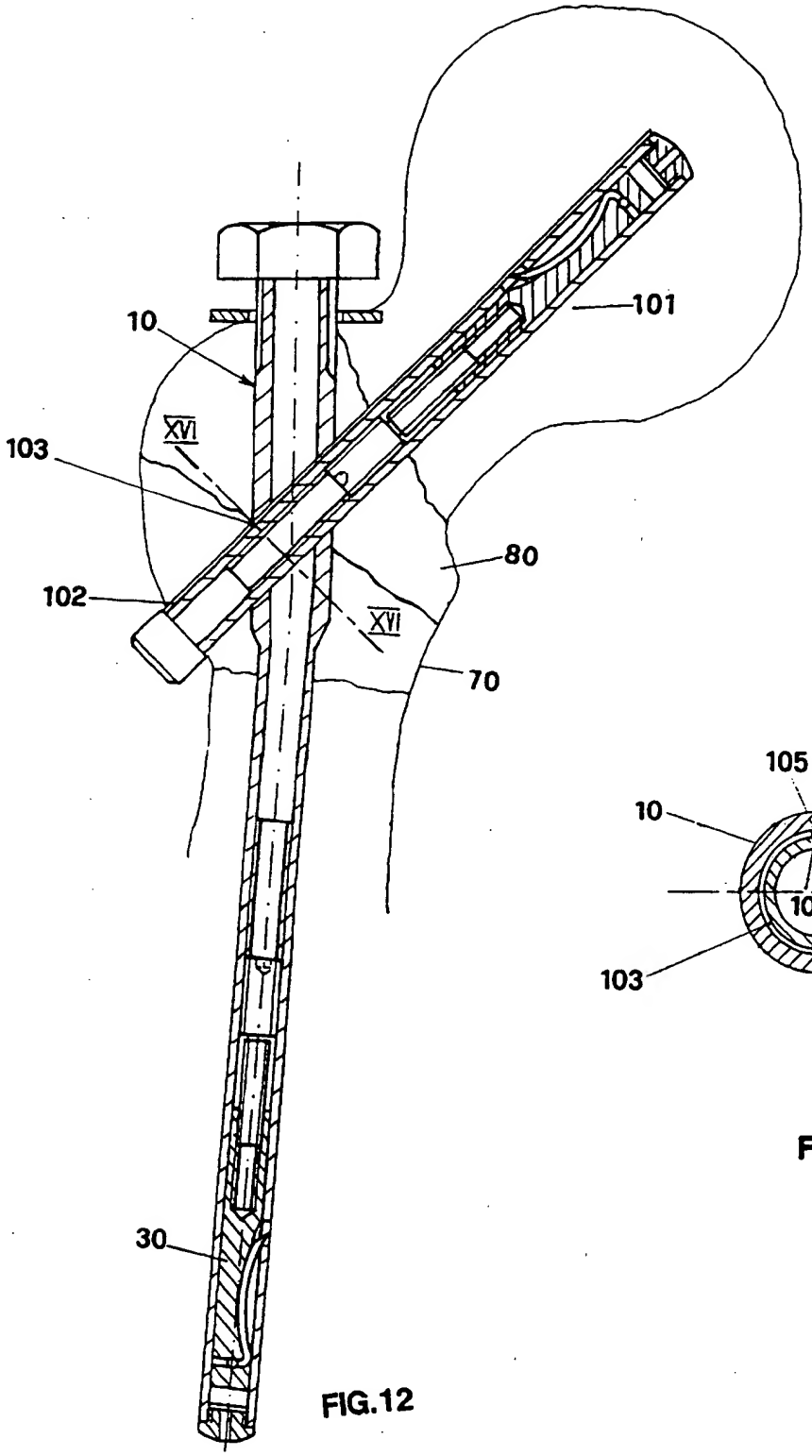

FIG.12

FIG.16

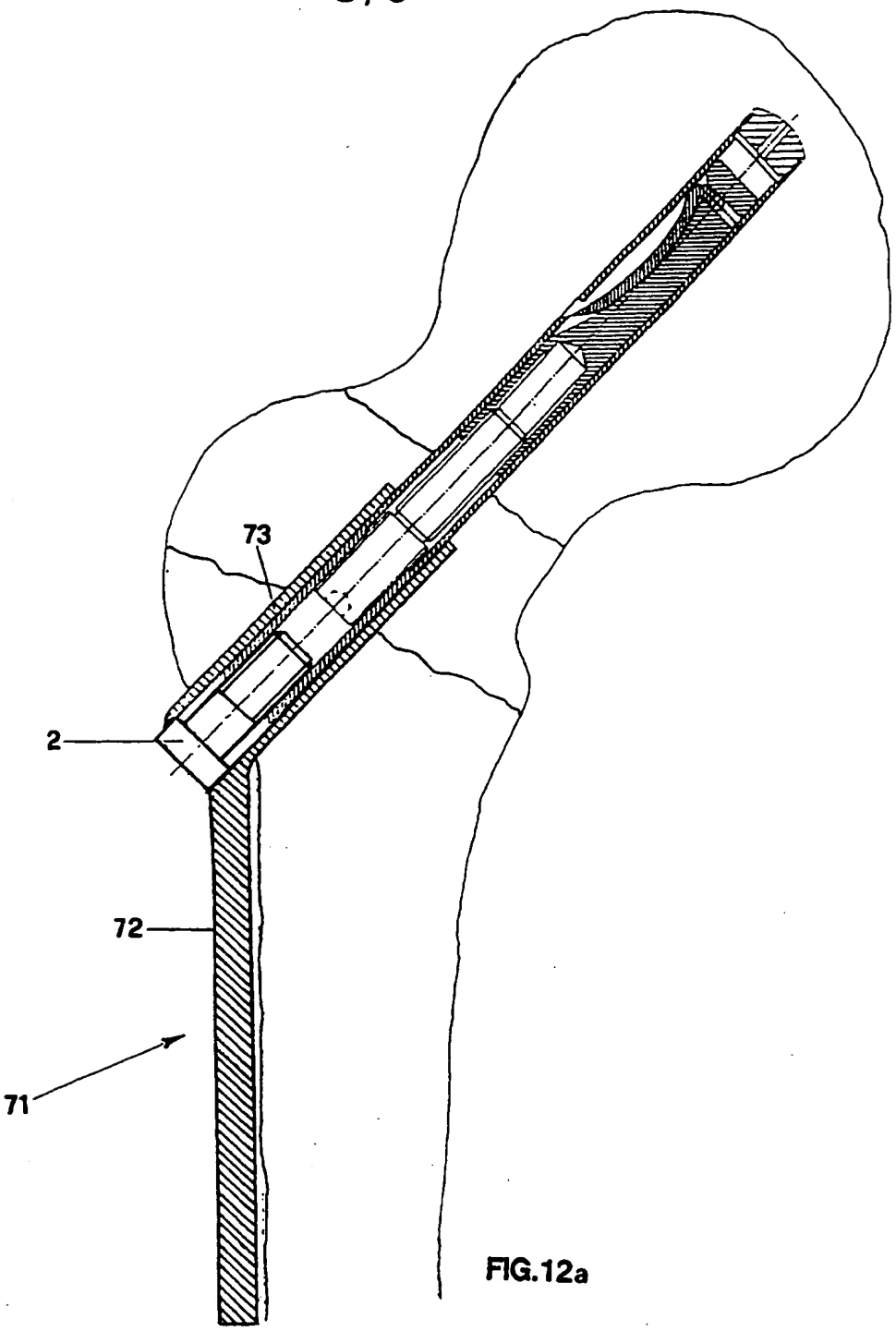

FIG.12a

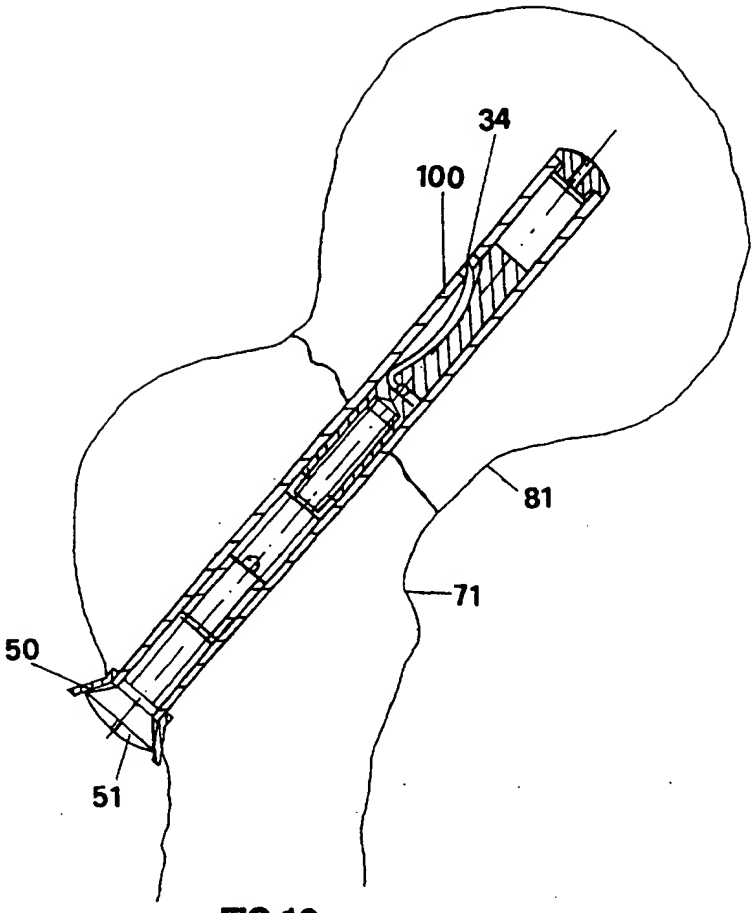

FIG.13

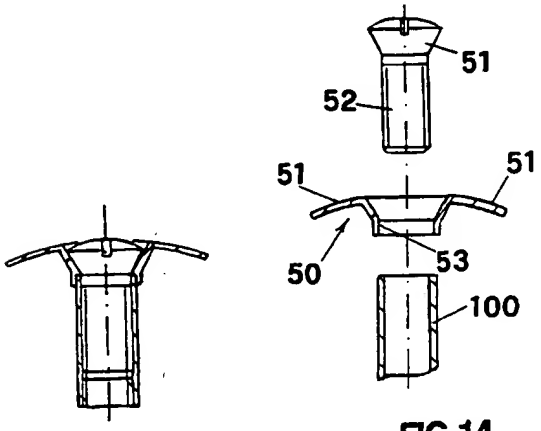

FIG.14

FIG.15

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 97/01675

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/72 A61B17/74

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 057 103 A (E.A.DAVIS) 15 October 1991 see figures 1,3A-3B ---	1,3,5,7, 8
A	US 4 862 883 A (Y.FREELAND) 5 September 1989 see figure 1 ---	1,4
A	FR 2 289 155 A (R.PARES AVILA) 28 May 1976 see page 2, line 12 - line 27; figures 1,4 ---	1,6
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A	CH 453 570 A (J.STEINHÄUSER) 14 June 1968 see claim; figures --- -/--	1,8

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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25 July 1997	01.08.97

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 97/01675

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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A	US 4 632 101 A (Y.FREEDLAND) 30 December 1986 see figure 10 -----	1,9

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